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10/596,009

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EXAMINER

BOSQUES, EDELMIRA

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,009	Applicant(s) CARREZ ET AL.	
	Examiner EDELMIRA BOSQUES	Art Unit 4128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>NPL, Foreign Reference</u> |

DETAILED ACTION

Claim Objections

1. Claims 13, 15-22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For example the container of claim 13, the enteral nutrition force feeder on claim 15, the syringe on claim 16, the probe in claim 17, the tube in claim 18, the connector of claim 19, the three way connector of claims 20-21 and the enteral nutrition lines of in claim 22, are not a further limitation of claim 1 but a different application of the limitations in claim 1.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 1, the recitation “an entry diameter and a diameter at the crest of the threads that are chosen in relation to the corresponding diameters of the standardized connectors so that the assembly of a male connector or female connector

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with a standardized female connector or standardized male connector respectively, is prevented because penetration of **the ferrule** of the male connector into the entry conduit of the female connector is impossible” is not supported in the specification in such a way that one skilled in the art to make and use the invention, since in the specification the applicant states that a female connector according to the invention is **allowed to penetrate by the ferrule of a standardized male connector**.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, the recitation “the head of the male tube being capable of penetrating with lateral sealing”, renders the claim indefinite since it is not clear if applicant is claiming a lateral sealing, also the claim recitation “*the ferrule of the male connector*” it is not clear if applicant is claiming the ferrule.

3. Claim 23 recites the limitations “the standardized connectors”, “the table”, and “the invention”. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 7-12, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy et al. (US 5535771) hereinafter Purdy in view of Bickford Smith et al. (US20060047551) hereinafter Smith.

Regarding to claim 1, (as presently and best understood) Purdy teaches a liquid transmission line connection apparatus or valve adapter (10, Refer to Fig. 2) comprising a **male connector** or male fitting (64, which includes conical coupling 26 and internal threaded area) and a **female connector** or cap (90) to be assembled and to be locked together in order to create a liquid transmission connection in the area of medical coupling, in which standardized male connectors and female connectors are currently used, in particular for an enteral nutrition line, with the female connector having as the standardized female connector a head (threaded area of the female adapter) that forms a conical entry conduit (*the female adapter fits within the male adapter threaded area which has a conical area (26) therefore the female connector will form a conical entry conduit when it is connected with in the male portion*) and which has an external thread (external threaded area of member 90) and with the male connector having as standardized male connector a projecting **conical tube** or passageway (26) that forms an entry conduit surrounded by a collar (*outside surface of the distal second end 24*) which forms a channel around the tube, and which has an internal thread (internal thread of member 24; See Fig. 2) with the head of the female tube being capable of penetrating into the channel of the male connector with the head of the male tube being capable of penetrating, with lateral sealing, into the entry conduit of the female

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connector and with the threads of the two connectors being capable of fitting together so as to lock the assembly. Purdy fails to specifically disclose that the connectors have an entry diameter and a diameter at the crest of the threads that are chosen in relation to the corresponding diameters of the standardized connectors so that the assembly of a male connector or female connector with a standardized female connector or standardized male connector respectively, is prevented because penetration of the ferrule (Ring or metal cap; Oxford Dictionary) of the male connector into the entry conduit of the female connector is impossible or because this penetration is halted by the head of the female connector butting against the collar of the male connector.

Smith teaches a standard luer can be provided with a latching mechanism in the form of a ring which prevents connection to a standard female luer connector (Refer to paragraph [0062]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the teachings of Smith into the Purdy's device to prevent an accidental connection of a different drug infusion.

Regarding to claims 2-3, (as presently and best understood) modified Purdy teaches all of the elements as discussed supra but fails to specifically disclose the liquid transmission line connection apparatus connectors have a taper other than 6% at the entry conduits. Smith, teaches luer connections having a different taper (i.e. 5% taper; Refer to paragraph [0027]). Since Smith teaches luer connections having a different taper than 6% it teach entry conduits having a taper falling within the range 4% and 8 - 10%. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to include a different taper as disclosed by Smith into the modified Purdy's device to avoid a misconnection with a standard luer.

Regarding to claim 4, (as presently and best understood) modified Purdy fails to specifically disclose that the conical entry conduits have a length of 6.5 mm. It has been held that changing the size or shape of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious to one of ordinary skill in the art to have modified the conical entry conduits of the Purdy's invention to have a length of 6.5 mm. Therefore the examiner takes official notice, it would have been obvious to one of ordinary skill in the art to have modified the modified Purdy to have a male connector having a male with a conical entry of 6.5 in order to provide a complementary connection with a mating female in order to avoid fluid leaks.

Regarding to claim 5 (as presently and best understood) modified Purdy fails to specifically disclose the liquid transmission line connection apparatus connectors in which the threads are double threads with a pitch of 5 mm. However it would have been an obvious matter of design choice to one of ordinary skill in the art to have modified the thread pitch to obtain optimum threaded seal within the connectors and to make a faster connection since the double thread permits, for example, a nut to advance faster through a double thread.

Regarding to claim 6 (as presently and best understood) modified Purdy fails to

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specifically disclose liquid transmission line connection apparatus in which the male connector has an entry diameter of 3.2 mm and a diameter at the crest of the threads of 5.8 mm and in which the female connector has an entry diameter of 3.5 mm and a diameter at the crest of the threads of 6.8 mm. However, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy device to have a male and female connectors as described in order to provide a complementary connection between the connection apparatus to avoid liquid leaks in the connection.

Regarding to claim 7, (as presently and best understood) modified Purdy fails to specifically disclose a liquid line transmission apparatus the male connector has a diameter of 7.0 mm at the base of the threads. However it has been held that changing the size of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy device with a male connector with diameter of 7.0 mm at the base of the threads to have the appropriate tension to hold the male connector when connected to a female connector.

Regarding to claim 8, (as presently and best understood) modified Purdy fails to specifically disclose a liquid line transmission apparatus the female connector has a

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diameter of 5.6 mm at the base of the threads. However it has been held that changing the size of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy device's the female connector with diameter of 5.6 mm at the base of the threads in order to have the female connector to have an appropriate fitting within a male connector of the invention providing appropriate tension in the connection to avoid liquid leaks.

Regarding to claim 9, (as presently and best understood) modified Purdy fails to specifically disclose liquid line transmission connection apparatus in which the male has an entry diameter of 4.5 mm and a diameter at the crest of the threads of 7.4 mm and in which the female connector has an entry diameter of 4.8 mm and a diameter at the crest of the threads of 8.2mm. However it has been held that changing the size of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy device in order to provide a complementary mating connection of conical entry conduits that will provide appropriate tension to avoid fluid leaks.

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Regarding to claim 10, modified Purdy fails to specifically disclose the male connector has a diameter of 8.4 mm at the base of the threads. However it has been held that changing the size of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy's device male connector with diameter 8.4 mm at the base of the threads in order to have a connection that will permit a larger amount of fluid flow.

Regarding to claim 11, modified Purdy fails to specifically disclose the female connector having a diameter of 7.2 mm at the base of the threads, however it has been held that changing the size of a device does not constitute a patentable advance because it at most relates to the size required for the device's use or is just one of numerous configuration a person of ordinary skill in the art would find obvious, the examiner takes official notice that it would have been an obvious matter of design choice to have modified the Purdy's device female connector with diameter of 7.2 mm to permit a mating connection with a mating male connector that will permit a larger amount of fluid flow.

Regarding to claim 12, (as presently and best understood) modified Purdy teaches that the liquid line transmission connection apparatus has **a rear channel** or

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fitting (60) for attaching fluid delivery devices to the fitting (Refer to column 4, lines 59-62).

Regarding to claim 19 (as presently and best understood) modified Purdy teaches a connector which has one end composed of a female connector (90), and another end which is capable of connecting to an enteral feed container (*Since fitting 60 is capable of adapting fluid delivery devices*; Refer to column 4, lines 59-62).

Regarding to claim 23 (as presently and best understood) modified Purdy teaches all of the elements of the “modified connectors” but fails to specifically disclose a set of connectors that include the standardized connectors. Smith teaches a set of connectors or kit of connectors (Refer to paragraphs [0024-0027]). Include the standardized connectors and a set of 'different connectors. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the standard connectors of Smith into the modified Purdy's device to have an alternate standard connector for a standard medical connecting line, thereby increasing the utility of the device.

3. Claims 13-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy in view of Felicelli et al. (US 6267154) hereinafter Felicelli.

Regarding to claims 13-14 (as presently and best understood), modified Purdy fails to specifically teach a container fitted with a female connector as previously

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described. Felicelli teaches a container (10) which can be a vial (Refer to Column 6, lines 12-13) (*vial is a small closed or closable vessel especially for liquids; vessel- a container (as a cask, bottle, kettle, cup, or bowl) for holding something, Merriam Webster Dictionary*) having a female Luer lock fitting (109) with threads (115) and a head (112) forming a conical entry (*Since head of the container in conjunction with the female lock area has a conical shape, See Fig. 2*) , adapted for receiving a male luer lock connector. (Refer to Column 4, lines 59-61, Figs. 2 and 2A). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a container with a female luer lock connector as described in Felicelli into the modified Purdy device as a sealing method to be used in containers in order to preserve a drug or a drug mixture within.

Regarding to claim 16, modified Purdy fails to specifically disclose a syringe equipped with a pipette for the take-up of enteral nutrition products, fitted with a male connector as described above. Felicelli teaches a syringe (182) with a pipette or barrel (184) and a male connector (193a, See Fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have a container with a male luer lock connector as described in Felicelli into the Purdy device as a complementary connection for the modified Purdy female connector in order to prevent the female connection with another type of male connector avoiding the connection of an inadequate treatment by mistake.

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4. Claims 15 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy in view of Harrison et al. (US 4390017) hereinafter Harrison.

Regarding to claim 15 modified Purdy fails to specifically disclose an enteral nutrition force-feeder, fitted with a female connector. Harrison teaches an enteral nutrition feeding container that uses a female/male connection (Refer to abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a female luer connector as described in modified Purdy's invention into an enteral nutrition force-feeder as described by Harrison since enteral nutrition feeding is the preferred route for nutrition treatment in intensive care patients, and since the use of such a connector can avoid a inadvertent misconnection in the enteral nutrition force-feeder.

Regarding to claim 22, modified Purdy fails to specifically disclose an enteral nutrition lines fitted with a male connector and a female connector. Harrison teaches an **enteral nutrition line** or tube body (17) that uses a **female/male connection** or male/female adapters (20 and 15); Refer to Column 2 lines 5-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a male and female connector of the modified Purdy into the Harrison enteral feeding system in order to avoid an erroneous connection with a medicament line having a standard luer connection instead of the nutritious infusion.

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5. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy (as discussed supra) in view of Whiteman (US 6407562).

Regarding claim 17, modified Purdy fails to specifically disclose a probe which has a connecting end composed of or equipped with a female connector as disclosed. Whiteman teaches a probe having a female connector (Refer to column 2, lines 52-54). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a female luer of modified Purdy in the Whiteman probe in order to avoid the connection of the probe with a standard male connector, to avoid misconnection errors.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy (as discussed supra, claim 1) in view of Guala (US 6673059).

Regarding claim 18 (as presently and best understood), modified Purdy fails to specifically disclose a tube which has one end equipped with a male connector (1) and an opposite end equipped with a female connector. Guala teaches a tube (L, See Fig 8) which has one end equipped with a male connector (1) and an opposite end equipped with a female connector (F). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the female and male connectors of Guala's tube with the female and male connectors of modified Purdy, to have enough tension between the connections to diminish or eliminate leaks between the connections.

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy (as discussed supra) in view of Cleveland (US 4238131)

Regarding to claim 20 modified Purdy fails to specifically disclose a three-way connector in which one channel is fitted with a male connector with each of the other two channels being equipped with a female connector. Cleveland teaches a two step branch attachment that comprises **two female connectors** (right and left ends 15, See Fig. 1) ends and a **male connector** or sleeve (28, See Fig. 1; *the sleeve is called the male connector since it has a narrowed portion (that is outwardly protruded) 22 and has threads 29*). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a male connector and two female connectors of modified Purdy into the Cleveland invention in order to have a three way connection that would avoid liquid leaks.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over modified Purdy (as described supra) in view of Blei (US 5921965).

Regarding to claim 21, modified Purdy fails to specifically disclose a three-way connector in which one channel is fitted with a female connector with each of the other two channels being equipped with a male connector. Blei teaches a three way connector or hub (123, See Fig. 1) in which one channel is fitted with a female connector (51) and each of the other two channels being equipped with a male connector (52 and 53, Refer to column 4 lines 1-5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a hub with three

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channels as disclosed by Blei in order to connect different lines with male and female connectors as taught in modified Purdy to have different drug infusions at the same time.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Refer to Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDELMIRA BOSQUES whose telephone number is (571)270-5614. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoa Huynh can be reached on 571-272-4888. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 4128

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